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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/446,783

05/16/2000

NEIL P. DESAI

VPHAR1460-2

2878

30542

7590

02/10/2004

FOLEY & LARDNER

P.O. BOX 80278

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/446,783	DESAI ET AL.	
	Examiner	Art Unit	
	Michael G. Hartley	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-35,46-67,70-105 and 107-120 is/are pending in the application.
- 4a) Of the above claim(s) 29-35,46-67,70-72,76-100 and 109-120 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-75,101-105, 107 and 108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Response to Amendment

The amendment filed 11/3/2003 has been entered.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The claimed priority in the amendment filed 11/3/2003 is improper and therefore priority has not been granted as set forth in the amendment. The receipt of the petition to accept an unintentionally delayed domestic priority claim under 37 CFR 1.78(a)(3) is acknowledged. However, the since claimed priority is not valid, it cannot be rectified by the petition. First, the statement "This application is a continuation of US provisional Application No. 60/051,021, filed 27 June 1997" is improper because a claim for domestic priority under 35 U.S.C. 119(e) must be filed within one year. The instant application has a filing date of May 16, 2000, which is more than one year from the filing date of the provisional, filed June 27, 1997. Second, the international application PCT/US98/13272 only claimed priority to 08/926,155, filed September 9, 1997 and 60/051,021, filed 27 June 1997. Therefore, the chain of priority of the international application is broken at 27 June 1997. Also, an international application can only claim priority back one year before the filing of the international application, see MPEP 1878, Item 2, thereby, breaking the chain of priority through the international application.

Thus, the only valid claim of priority in the present amendment is the statement, "This application is...a 371 of PCT/US98/13272, filed 26 June 1998, which is a continuation-in-part of U.S. Patent Application Serial No. 08/926,155, filed 9 September 1997, now U.S. Patent No. 6,096,331." Therefore, the priority date of the claimed subject matter is established as 9 September 1997.

Claim Rejections - 35 USC § 112

The amendment filed 11/03/2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as

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follows: "the contents of each of which are hereby incorporated by reference in their entirety" which was inserted at the end of the amendment to the specification. For example, MPEP 201 states:

A priority claim under 35 U.S.C. 120 in a continuation or divisional application does not amount to an incorporation by reference of the application(s) to which priority is claimed.

For the incorporation by reference to be effective as a proper safeguard against the omission of a portion of a prior application, the incorporation by reference statement must be included in the specification-as-filed, or transmittal letter-as-filed, or in an amendment specifically referred to in an oath or declaration executing the application.

An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. 132(a)). If an incorporation by reference statement is included in an amendment to the specification to add a benefit claim under 35 U.S.C. 120 after the filing date of the application, the amendment would not be proper. When a benefit claim under 35 U.S.C. 120 is submitted after the filing of an application, the reference to the prior application cannot include an incorporation by reference statement of the prior application. See *Dart Indus. v. Banner*, 636 F.2d 684, 207 USPQ 273 (C.A.D.C. 1980).

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In *re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See MPEP § 608.01(p).

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 73-75, 101-104, 107 and 108 are rejected under 35 U.S.C. 102(b) as being anticipated by Desai (US 5,439,686), for the reasons set forth in the office action mailed 7/1/2003.

Applicant's arguments filed 11/3/2003 have been fully considered but they are not persuasive.

Applicant asserts that the claimed priority to 2/22/93 renders the above rejection moot, since Desai is no longer prior art.

This is not found persuasive because the claimed priority is not valid to 2/22/93, but only to 9/9/1997 as set forth in the amendment. It does not appear that applicant can claim priority prior to 27 June 1997, since this application is a 371 of a PCT application, which can only claim priority back one year from the filing of the PCT. Thus, with the established valid priority date of 9/9/1997 in the amendment filed 11/3/2003, as stated above, Desai is prior art under 35 USC 102(b).

Claims 73-75, 101-104, 107 and 108 are rejected under 35 U.S.C. 102(e) as being anticipated by Yen (US 5,945,033), for the reasons set forth in the office action mailed 7/1/2003.

Applicant's arguments filed 11/3/2003 have been fully considered but they are not persuasive.

Applicant asserts that the claimed priority to 2/22/93 renders the above rejection moot, since Yen is no longer prior art.

This is not found persuasive because the claimed priority is not valid to 2/22/93, but only to 9/9/1997 as set forth in the amendment. It does not appear that applicant can claim priority prior to 27 June 1997, since this application is a 371 of a PCT application, which can only claim priority back one year from the filing of the PCT. Thus, with the established valid priority date of 9/9/1997 in the amendment filed 11/3/2003, as stated above, Yen is prior art under 35 USC 102(e).

Applicant also asserts that Yen fails to disclose a drug in nanoparticle size and a protein.

This is not found persuasive because Yen clearly discloses drug containing nanoparticles which include a protein, see abstract. Applicant's assertion that the claims specifically require that, only the

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drug is a nanoparticle and not the combination of drug and protein is not seen. Clearly, a drug contained in a protein nanoparticle is within the scope of a formulation of at least one protein, wherein said formulation comprises drug nanoparticles. Clearly the formulation of drug protein nanoparticles of Yen are drug nanoparticles. The claim does not require the drug to be independently, from the protein, in nanoparticle form.

Claims 73, 102, 103, 107 and 108 are rejected under 35 U.S.C. 102(e) as being anticipated by Friedman (US 5,897,879), for the reasons set forth in the office action mailed 7/1/2003.

Applicant's arguments filed 11/3/2003 have been fully considered but they are not persuasive.

Applicant asserts that the claimed priority to 2/22/93 renders the above rejection moot, since Friedman is no longer prior art.

This is not found persuasive because the claimed priority is not valid to 2/22/93, but only to 9/9/1997 as set forth in the amendment. It does not appear that applicant can claim priority prior to 27 June 1997, since this application is a 371 of a PCT application, which can only claim priority back one year from the filing of the PCT. Thus, with the established valid priority date of 9/9/1997 in the amendment filed 11/3/2003, as stated above, Friedman is prior art under 35 USC 102(e).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 73-75 and 101-104, 107 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 6,143,276), for the reasons set forth in the office action mailed 7/1/2003.

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Claim 105 is rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Unger as applied to claims 73-75 and 101-104 and above, and further in view of Jones (US 5,731,355), for the reasons set forth in the office action mailed 7/1/2003.

Applicant's arguments filed 11/3/2003 have been fully considered but they are not persuasive.

Applicant asserts that the claimed priority to 2/22/93 renders the above rejection moot, since Unger and Jones are no longer prior art.

This is not found persuasive because the claimed priority is not valid to 2/22/93, but only to 9/9/1997 as set forth in the amendment. It does not appear that applicant can claim priority prior to 27 June 1997, since this application is a 371 of a PCT application, which can only claim priority back one year from the filing of the PCT. Thus, with the established valid priority date of 9/9/1997 in the amendment filed 11/3/2003, as stated above, Unger and Jones are prior art under 35 USC 103.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-

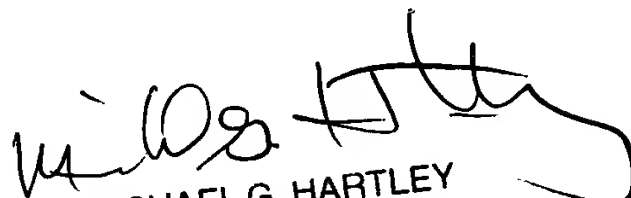
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2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

MH

December 2, 2003


MICHAEL G. HARTLEY
PRIMARY EXAMINER